Sertifikaat

REPUBLIEK VAN SUID-AFRIKA

PATENTKANTOOR

DEPARTEMENT VAN HANDEL EN NYWERHEID

Certificate

REPUBLIC OF SOUTH AFRICA

PATENT OFFICE

DEPARTMENT OF TRADE AND INDUSTRY

Hiermee word gesertifiseer dat
This is to certify that IB00/01066

the documents attached hereto are true copies of the Forms P2, P6, provisional specification and drawings of South African Patent Application No. 99/4910 filed in the name of DRUKKER INTERNATIONAL B.V. 4

REC'D 13 SEP 2000
WIPO PCT

Filed : 30.07.99

Entitled : A CUTTING BLADE FOR A SURGICAL INSTRUMENT

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

Get[illegible]ETORIA in die Republiek van Suid-Afrika, hierdie 3rd dag van August 2000
S[illegible] in the Republic of South Africa, this day of

Registrateur van Patente
Registrar of Patents

G.P.-S. 019-0096

FORM P.2

REPUBLIC OF SOUTH AFRICA	REGISTER OF PATENTS	PATENTS ACT, 1

OFFICIAL APPLICATION	LODGING DATE: PROVISIONAL	ACCEPTANCE DATE
21 01 99/4910	22 30-07-99	47
INTERNATIONAL CLASSIFICATION	**LODGING DATE: COMPLETE**	**GRANTED DATE**
51	23	

FULL NAME(S) OF APPLICANT(S)/PATENTEE(S)

71 DRUKKER INTERNATIONAL B.V.

APPLICANTS SUBSTITUTED:	DATE REGISTERED
71	

ASSIGNEE(S)	DATE REGISTERED
71	

FULL NAME(S) OF INVENTOR(S)

72 GODFRIED, Herman Philip

PRIORITY CLAIMED	COUNTRY	NUMBER	DATE
N.B. Use International abbreviation for country (see Schedule 4)	33 NIL	31 NIL	32 NIL

TITLE OF INVENTION

54 A CUTTING BLADE FOR A SURGICAL INSTRUMENT

ADDRESS OF APPLICANT(S)/PATENTEE(S)

DEBID HOUSE, CNR AMETHYST STREET AND CROWNWOOD ROAD, THETA, JOHANNESBURG, GAUTENG, REPUBLIC OF SOUTH AFRICA

ADDRESS FOR SERVICE	S AND F REF
74 **SPOOR AND FISHER, SANDTON**	JP/D 1614/CB/nh

PATENT OF ADDITION NO.	DATE OF ANY CHANGE
61	
FRESH APPLICATION BASED ON	**DATE OF ANY CHANGE**

SPOOR AND FISHER

REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978
APPLICATION FOR A PATE[illegible]
AND ACKNOWLEDGEMENT OF R[illegible]
(Section 30 (1) – Regulation 22)

REPUBLIC OF SOUTH AFRICA REVENUE FORM P.1
30.07.99
R 060.00
HASP 525
INKOMSTE
REPUBLIEK VAN SUID AFRIKA

The granting of a patent is hereby requested by the undermentioned applicant on the basis of the present application filed in duplicate

OFFICIAL APPLICATION NO.		S AND F REFERENCE
21 01	994910	JP/D 1614/CB/nh

FULL NAME(S) OF APPLICANT(S)

71	DRUKKER INTERNATIONAL B.V.

ADDRESS(ES) OF APPLICANT(S)

	DEBID HOUSE, CNR. AMETHYST STREET AND CROWNWOOD ROAD, THETA, JOHANNESBURG, SOUTH AFRICA

REGISTRAR OF PATENTS, DESIGNS, TRADE MARKS AND COPYRIGHT
1999 -07- 30
REGISTRATEUR VAN PATENTE, MODELLE, HANDELSMERKE EN OUTEURSREG

TITLE OF INVENTION

54	A CUTTING BLADE FOR A SURGICAL INSTRUMENT

THE APPLICANT CLAIMS PRIORITY AS SET OUT ON THE ACCOMPANYING FORM P.2 THE EARLIEST PRIORITY CLAIM IS:

COUNTRY:	NUMBER:	DATE:
NIL	NIL	NIL

~~THIS APPLICATION IS FOR A PATENT OF ADDITION TO PATENT APPLICATION NO.~~

21	01

~~THIS APPLICATION IS A FRESH APPLICATION IN TERMS OF SECTION 37 AND IS BASED ON APPLICATION NO.~~

21	01

THIS APPLICATION IS ACCOMPANIED BY:

- [x] 1. A single copy of a provisional specification of 8 pages.
- [ ] 2. Drawings of 0 sheets.
- [ ] 3. Publication particulars and abstract (Form P.8 in duplicate).
- [ ] 4. A copy of Figure of the drawings (if any) for the abstract.
- [ ] 5. An assignment of invention.
- [ ] 6. Certified priority document(s) .
- [ ] 7. Translation of the priority document(s).
- [ ] 8. An assignment of priority rights.
- [ ] 9. A copy of the Form P.2 and the specification of S.A. Patent Application No.
- [ ] 10. A declaration and power of attorney on Form P.3.
- [ ] 11. Request for ante-dating on Form P.4.
- [ ] 12. Request for classification on Form P.9.
- [x] 13. Form P.2 in duplicate.

74 ADDRESS FOR SERVICE: SPOOR AND FISHER, SANDTON

Dated: 30 July 1999

SPOOR AND FISHER
PATENT ATTORNEYS FOR THE APPLICANT(S)

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REGISTRAR OF PATENTS

SPOOR AND FISHER

FORM P.6

REPUBLIC OF SOUTH AFRICA
PATENTS ACT,1978

PROVISIONAL SPECIFICATION

(Section 30(1) – Regulation 27)

OFFICIAL APPLICATION NO.			LODGING DATE	
21	01	99/4910	22	30-07-99

FULL NAME(S) OF APPLICANT(S)

71	DRUKKER INTERNATIONAL B.V.

FULL NAME(S) OF INVENTOR(S)

72	GODFRIED, Herman Philip

TITLE OF INVENTION

54	A CUTTING BLADE FOR A SURGICAL INSTRUMENT

BACKGROUND TO THE INVENTION

THIS invention relates to a cutting blade for a surgical instrument in which the cutting blade is formed of a hard transparent, crystalline material, such as diamond sapphire or garnet, on the surface of which is provided a layer of fluorine atoms chemically bonded to the surface.

Surgical blades are extremely sharp in order to minimise tissue damage along a line of incision. In order to achieve the desired sharpness of a cutting blade materials of choice for the manufacture of cutting blades are hard materials of a crystalline nature, such as diamond or sapphire.

During use blood and other bodily fluids and materials often stick to the facets of a cutting blade thereby reducing its effectiveness. It is known to prevent this from happening or at least reduce the sticking effect and facilitate cleaning of the blade by, for instance, wiping the blade with a suitable material or sticking it into a block of suitable plastic foam, for example polystyrene.

The problem of blood sticking to or coagulating on the surface of a cutting blade may be aggravated under conditions where the blade temperature exceeds the temperature at which blood starts to coagulate, namely 55 °C. This may be caused by deliberate heating of the surgical blade to induce

coagulation; by high intensity light sources used in conjunction with the blade or by the simultaneous use of a laserbeam, either through the cutting blade or applied separately.

South African provisional patent application no. 99/4256, also filed by the applicant in this instance, describes a cutting blade for a surgical instrument in which the cutting blade is formed of diamond and laser radiation is transmitted through the blade in order to provide a cauterization effect along a line of incision. This earlier application is incorporated herein by reference. The laser radiation passing through the cutting blade which forms the subject of this invention would cause heating of the blade which encourages blood sticking and coagulating on the surface of the blade.

SUMMARY OF THE INVENTION

According to the invention there is provided a method of forming a protective layer of fluorine atoms on a cutting blade for a surgical instrument in which the blade is formed of hard, transparent, crystalline material, such as diamond, sapphire or garnet, the method comprising the steps of:

a) placing the blade in a plasma reactor;

b) plasma cleaning the blade;

c) coating the blade in a plasma of carbon fluoride (C_nF_m) gas.

Preferably, the carbon fluoride (C_nF_m) gas is C_3F_8, alternatively C_2F_4 or C_2F_6.

The method may include the step of chemically cleaning the blade.

Typically, the coating takes place at a pressure of 0,1 to 2 mbar, for a period of 30 to 180 minutes and at a power level of 50 to 2000 watts.

Conveniently, the cleaning takes place in a plasma of air, oxygen, argon or a mixture thereof.

According to a second aspect of the invention there is provided a cutting blade for a surgical instrument, the cutting blade being formed of a hard, transparent, crystalline material, such as diamond, sapphire or garnet, on the surface of which is provided a protective layer of fluorine atoms formed in accordance with the method described above.

Preferably, the blade is formed of natural, monocrystalline synthetic or polycrystalline synthetic diamond or sapphire.

Various embodiments of the invention are described in detail in the following passages of the specification. The described embodiments are merely illustrative of how the invention might be put into effect and should not be seen as limiting on the scope of the invention.

DESCRIPTION OF AN EMBODIMENT

In general terms this invention relates to a method of forming a protective layer of fluorine atoms on a cutting blade for a surgical instrument in which the surgical blade is formed of a hard, transparent crystalline material such as diamond, sapphire or garnet. The purpose of the layer is to reduce the

sticking effect of blood and bodily fluids and materials to the blade during use. The layer should be of minimum thickness to minimise the reduction in sharpness of the blade. It is envisaged that this may be achieved according to the invention either by minimising the thickness of the layer (in the extreme case one atomic layer of fluorine) or by polishing a micro facet on one or both sides of the cutting edge after the coating has been applied.

The method of the invention is in essence a plasma coating method involving the following steps:

1. Chemically cleaning the blade.

2. Placing the cutting blade in a plasma reactor.

3. Plasma cleaning of the blade. This is done in a plasma of air, oxygen, argon or a mixture thereof for 5 to 20 minutes at approximately 1 mbar pressure and a power level of approximately 500 watts (ranges are not critical). The power is switched on at a duty cycle of 5 % to 50 % to prevent overheating. This cleaning step is essential if ultimately good adhesion of the fluorine layer is to be achieved.

4. Coating the blade in a plasma of C_3F_8. The process conditions of this coating step are a pressure of 0.1 to 2 mbar for a period of 30 to 180 minutes at a power level between 50 and 2000 watts.

The above description is a description of one method of putting the process of the invention into effect and of variations on the specific process conditions described above.

Two different approaches may be used in the process described above:

1. The chemical structure of the diamond or other hard, crystalline material is modified such that it terminates with fluorine atoms, instead of the more usual hydrogen and/or oxygen. This can be achieved by exposing the surface of the material, such as diamond, to atomic fluorine at a range of temperatures, between 273 and 573K. The preferred deposition method for the fluorine atomic layer onto the surgical blade is plasma treatment. In this method the surgical blade is exposed to a plasma excited in an atomic fluor generating substance such as SF_6, NF_3, HF or F_2. Argon may be introduced into the plasma to reduce the deposition rate to controllable levels.

2. The surface is coated with a fluorocarbon polymer layer. This can be achieved by the known technique of plasma polymerization using precursors such as tetrafluoroethene. This process is described in the article entitled "Fundamentals of Plasma Chemistry and Technology" H.V. Boenig, Pub Technomatic, 1988 and the other references referred to in this document, which are all incorporated herein by reference.

   The preferred deposition method for the fluorocarbon polymer layer onto the surgical blade is plasma treatment. In this method the surgical blade is exposed to a plasma excited in a carbon fluoride gas. Argon may be introduced into the plasma to reduce the deposition rate to controllable levels.

The thickness of the fluorocarbon polymer layer created by this process is a function of the time for which the blade is subjected to the process. The coating thickness can vary from a few nanometers to hundreds of nanometers. Thinner coatings are more desirable so as not to blunt the cutting edge of the blade and limit laser light absorption.

The polymer is deposited from a plasma excited from one of the following gasses:

C_2F_4, C_2F_6, C_3F_8.

The layer thickness is typically between 5 nanometers and 10 microns. A micro facet of between 5 and 50 microns is polished on one or both sides of the cutting edge after the layer has been formed.

In addition to the method described above other processes may also be used to achieve the desired layer of fluorine atoms on the surface. One such method is to apply teflon to the surface of the cutting blade by heating the blade in a C_2F_4 environment. This induces polymerisation of the C_2F_4 on the hot surfaces to form a layer of fluorine atoms. Alternatively, parylene may be applied in a similar manner. In this variation on the process a (chemically inert) parylene dimer is "cracked" in a hot oven zone and the resultant reactive monomers are allowed to polymerise on the surface of the blade which is at a cooler temperature.

The cutting blades to which this process may be applied are formed of hard, transparent crystalline material. Typically this material is natural,

monocrystalline synthetic or polycrystalline synthetic diamond or sapphire. However, other materials could also be used such as hard crystalline simple oxides such as zirconia ($Zr0_2$), yttria (Y_20_3), garnets, most notably YttriumAluminumGarnet, LutetiumAluminumGarnet, vanadates and aluminumoxides (such as YttriumAluminumOxide.) Other hard infrared transparent crystals which may also be appropriate for the process are, orthosilicates.

The method which forms the subject of this invention can be applied to a wide range of cutting blades operating in a range of laser wavelengths, such as those which are described in South African provisional patent application no.99/4256.

DATED THIS 30th DAY OF JULY 1999

SPOOR AND FISHER
APPLICANTS PATENT ATTORNEYS